Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the efficacy of topical Nigella Sativa product and gabapentin capsule on diabetic peripheral neuropathy

Protocol summary

Study aim
Determining and comparing the mean score of neuropathy severity in study groups: topical Nigella Sativa product, placebo (topical) and gabapentin capsule

Design
A randomized controlled clinical trial with parallel, double-blind, randomized groups

Settings and conduct
The study will be conducted at the Yazd Diabetes Research Center. Patients will be diagnosed by a neurologist. We then randomly divide the participants into three groups. The first group will receive topical Nigella Sativa (ointment), the second group topical placebo and the last group will receive gabapentin 300 mg capsules. Patients will be followed for 8 weeks. The first follow-up is at the end of the second week (to check for complications and adherence of patients) and the second follow-up is at the end of the fourth week and the third follow-up is at the end of the 8 weeks.

Participants/Inclusion and exclusion criteria
Inclusion criteria : Type 2 diabetes mellitus with diabetic neuropathy diagnosed by neurologist resident of Yazd controlled glucose (HbA1c less than 9) exclusion criteria : Spinal Disorders and Discopathy Heart disorder Renal disorder Liver disorder Active foot ulcer Autoimmune diseases mental illnesses Drug and alcohol addiction Skin diseases in the area of drug use Severe foot vascular disorders

Intervention groups
The first group : topical Nigella Sativa (ointment) The second group : topical placebo (ointment) The last group : gabapentin 300 mg

Main outcome variables
Severity of neuropathy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160221026684N2**
Registration date: **2022-02-22, 1400/12/03**
Registration timing: **retrospective**

Last update: **2022-02-22, 1400/12/03**
Update count: **0**

Registration date
2022-02-22, 1400/12/03

Registrant information

Name
Seyed Ali Khodaie

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 35 3728 0215

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sa.khodaei@shahed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-20, 1399/02/01

Expected recruitment end date
2022-02-19, 1400/11/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the efficacy of topical Nigella Sativa product and gabapentin capsule on diabetic peripheral neuropathy

Public title
The effect of Nigella Sativa on diabetic neuropathy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Type 2 diabetes mellitus with diabetic neuropathy diagnosed by neurologist resident of Yazd controlled glucose (HbA1c less than 9)
Exclusion criteria:
Spinal Disorders and Discopathy Heart disorder Renal disorder Liver disorder Active foot ulcer Autoimmune diseases mental illnesses Drug and alcohol addiction Skin diseases in the area of drug use Severe foot vascular disorders
Age
From **30 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Random method: Simple random Random double blind Referral by a neurologist 120 envelopes: 40 pieces A (treatment), 40 pieces B (placebo), 40 pieces C (gabapentin) sealed and closed, in front of the secretary. Upon arrival, each patient is given a random envelope. The secretary only provides packages containing materials A, B and C to patients and does not know their contents.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, only the principal investigator and outcome assessor are aware of the contents of the envelope. Patients and others involved in the design have no information about the type of material in the envelopes. Drug and placebo are similar in shape, color, odor, packaging, and appearance, and blinding has been performed between them. Gabapentin capsule group is the standard treatment.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of shahid sadoughi university of medical sciences
Street address
Diabetes Research Center, Talar-e-Honar Alley, Shahid Sadoughi Blvd, Yazd
City
yazd
Province
Yazd
Postal code
8917693571
Approval date
2019-07-30, 1398/05/08
Ethics committee reference number
IR.SSU.REC.1398.077

Health conditions studied

1

Description of health condition studied
diabetic neuropathy
ICD-10 code
E08.40
ICD-10 code description
Diabetes mellitus due to underlying condition with diabetic neuropathy, unspecified

Primary outcomes

1

Description
Severity of peripheral neuropathy
Timepoint
before intervention and 2, 4 , 8 weeks after intervention
Method of measurement
MICHIGAN NEUROPATHY SCREENING INSTRUMENT

Secondary outcomes

1

Description
HbA1c
Timepoint
before intervention and 8 weeks after intervention
Method of measurement
Chromatography (HPLC)

Intervention groups

1

Description

First intervention group: topical Nigella Sativa product. This product is prepared from aqueous extract of black seed and base cream in the form of 10% ointment, used twice a day (morning and night before bed) and for 8 weeks on both patients' feet. The amount of ointment used each time is the size of a fingertip, which is massaged from top to bottom. The drug is formulated in Behdanebaran pharmaceutical company.

Category

Treatment - Drugs

2

Description

Control group: topical placebo- This product is prepared from a base cream and black paint in the form of an ointment, used twice a day (morning and night before bed) and for 8 weeks on both patients' feet. The amount of ointment used each time is the size of a fingertip, which is massaged from top to bottom. The placebo is formulated in Behdanebaran pharmaceutical company

Category

Placebo

3

Description

Second intervention group: Gabapentin 300 mg capsules- In this group, patients receive a 300 mg gabapentin capsule orally every night before bed for 8 weeks. Capsules are manufactured by JALINOUS Pharmaceutical Company.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Diabetes Research Center
Full name of responsible person
seyedalikhodaie
Street address
Talar-e-Hanar Alley, North Shahid Sadoughi Blvd
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yazd University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
seyedalikhodaie
Position
Non-Academic Specialist Physician
Latest degree
Ph.D.
Other areas of specialty/work
Traditional Medicine
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Nigella Sativa data Data on the main outcome will be made available to other researchers with the permission of the first executor.
When the data will become available and for how long
starting 6 months after publication
To whom data/document is available
people working in academic institutions
Under which criteria data/document could be used
Coordinate with project analyzer
From where data/document is obtainable
dr seyed ali khodaie :03537280215
dr.seyedalikhodaie@yahoo.com
What processes are involved for a request to access data/document
Request data from Yazd University of Medical Sciences, approval of the director of the Diabetes Research Center, approval of the first executor of the project
Comments